510(K) SUMMARY

Date Prepared:

June 19, 2009

Owner and Contact Person:

Owner/Operator:	Owner/Operator # 9098803 Fenwal, Inc. Three Corporate Drive Lake Zurich, IL 60047
Contact Name:	Tammy Davis
Title:	Regulatory Affairs Specialist
Address:	Three Corporate Drive Lake Zurich, IL 60047
Telephone:	(847) 550-7955
Fax:	(847) 550-2960
E-mail:	tammy.davis@fenwalinc.com

Device Name(s):

(4R2105) Bone Marrow Collection Stand

(4R2107H) *Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters

(4R2108H) Ancillary Bone Marrow Collection Container with Flexible Pre-Filter

*The subject of this 510(k)

Common Name:

Bone Marrow Collection Kit and Accessories

Classification Name:

Unclassified – Pre-Amendment

Classification Panel Name:

80 LWE (General Hospital) Bone Marrow Collection/Transfusion Kit

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:

Fenwal, Inc. is claiming substantial equivalence of the revised Bone Marrow Collection Kit and Accessories with the currently marketed version of the Bone Marrow Collection Kit and Accessories cleared under 510(k) BK940005 on May 18, 1994 and the original version cleared under 510(k) K871198 on November 12, 1987.

Device Description:

This product is a system consisting of a flexible plastic collection bag, a series of flexible, inline filters for the removal of material greater than or equal to 200 microns, flexible plastic containers for the collection of the filtered product, sterile wraps for use as a sterile field, and a stainless steel sterilized stand for the support of the collection bag.

The configuration of the Bone Marrow Collection Kits consists of:

1 – 1.2 Liter Collection Container with 850 micron Pre-filter
2 – 500 micron Plastic Mesh Filters in flexible plastic housing (red)
1 – 200 micron Plastic Mesh Filters in flexible plastic housing (blue)
3 – 600 mL Transfer Pack Containers
1 – 2000 mL Transfer Pack Container
1 – Plastic Pouch containing four non-vented tip protectors
2 – Sterile Wraps

When in use the collection container is placed in the sterilized stand near the intended site of marrow procurement and the outlet clamp is closed. Marrow is passed by gravity through the filters and collected in the transfer pack unit. At the completion of marrow

harvest or when the container is full, the snap-lock lid on the collection container is closed and the container is removed from the stand and transferred to the area where the filtration procedure is to be performed.

The Bone Marrow Collection Kit and Accessories is currently unclassified as a device. The classification name is Bone Marrow Collection/Transfusion Kit.

Modification to the Existing Device:

The Bone Marrow Collection Kit and Accessories was modified to change the 200 micron mesh filter. The Ethylene Tetrafluoroethylene (ETFE) mesh monofilament filter in the 200 micron filter will be replaced with a Polyvinylidene Fluoride (PVDF) mesh monofilament filter meeting the same physical characteristics as the current mesh.

Statement of Intended Use:

The Bone Marrow Collection Kit and Accessories are used for the collection and filtration of aspirated bone marrow in preparation for bone marrow transplantation.

Technological Characteristics:

The technological characteristics of the Bone Marrow Collection Kit and Accessories remain the same as the currently marketed device. The modification made to 200 micron filter in the Bone Marrow Collection Kit was designed to meet the same requirements and specifications as the filter in the current device. This modification maintains substantial equivalence by meeting the same intended use with the same technology.

Design Control Activities:

The modification made to 200 micron filter in the Bone Marrow Collection Kit and Accessories was managed under the change control process. Potential risks associated with this change were identified. Performance studies and functional testing were conducted to show that the new filter material was biocompatible and functionally comparable to the old material.

Conclusion:

The original devices (4R2105, 4R2107, and 4R2108) listed in this summary have been cleared under 510(k) numbers K871198 and BK940005, which showed the product to be safe and effective. The filter modification made to the Bone Marrow Collection Kit and Accessories did not impact the intended use, fundamental technology, safety or efficacy of the device and therefore the device remains substantially equivalent to the currently marketed device.